

### **REMARKS**

Applicant respectfully requests reconsideration. Applicant has amended the specification to include priority application information. Claims 1-44 are pending in this application. Claims 13-44 have been cancelled. Claims 1, 2, 6 and 10 are amended herein. Claims 1 and 2 have been amended to recite the effective amount of the anti-fungal azole compound. Claims 6 and 10 have been amended to clarify claim language and minor typographical errors. Claims 1-12 are pending in this application with claim 1 being an independent claim. No new matter has been added.

### **Election/Restrictions**

The Office Action acknowledges Applicant's election without traverse of Group II, drawn to a method of treating a subject having a non-fungal induced mucositis of the distal intestinal tract (Page 2 of the Office Action). Applicant respectfully submits that in the reply mailed on July 20, 2009, the Applicant had elected Group I, (claims 1-12) drawn to a method of treating a subject having a non-fungal induced mucositis of the distal intestinal tract. Applicant assumes that the Office Action's acknowledgement of the election Group II was a typographical error, and that acknowledgement of Group I was intended.

### **Priority**

The Office Action indicates that Applicant has not properly claimed the benefit of the prior-filed provisional application (US 60/504,516) filed on September 18, 2003. A reference to the prior-filed provisional application has been included in the Supplemental Application Data Sheet submitted herewith. Applicant has also amended the specification to include the priority application information. Applicant respectfully requests entry of this amendment. No new matter has been added.

### **Rejections Under 35 U.S.C. §102**

Claims 1, 3-5, 7-9, 11, and 12 are rejected under 35 U.S.C. 102(b) as anticipated by Mimura, et al. (Alimentary Pharmacology and Therapeutics, 2002).

The Office Action alleges that “Mimura, et al., teach that antibiotics, such as metronidazole, are effective for the treatment of pouchitis.” According to the Office Action, “some of the drugs would fail to be absorbed and would thus be locally administered to the distal intestinal tract” (page 4 of the Office Action).

Without conceding the correctness of the rejection and solely in the interest of expediting prosecution, claim 1 has been amended to include the limitation that the effective amount comprises 2,000 mg to 10,000 mg of the anti-fungal azole compound. Support for this amendment can be found, for example, on page 7, lines 24-26 of the application.

The Office Action asserts, and Applicant agrees that Mimura et al. does not disclose a dose of an anti-fungal azole ranging between about 2,000 mg to 10,000 mg for treating non-fungal induced mucositis (page 5 of the Office Action). Thus, Mimura et al. does not anticipate the currently amended pending claims.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. §103**

As discussed above, without conceding the correctness of the rejections and solely in the interest of expediting prosecution, claim 1 has been amended to include the limitation that the effective amount of the anti-fungal azole compound is in the range of 2,000 mg to 10,000 mg.

Mimura et al. teaches that the administration of 400 or 500 mg of metronidazole tablets twice a day is highly effective for treating patients with pouchitis. Mimura et al. does not teach or suggest administering more than 400 or 500 mg metronidazole tablets twice a day. Moreover, it was known in the art at the time of filing of this application that high conventional dosing of anti-fungal azole compounds was associated with undesired side effects. Accordingly, based on the teachings of Mimura et al. and what was known in the art at the time of filing of this application, one of ordinary skill in the art would not have been motivated or have a reason to use a higher dosage of the anti-fungal azole compound for direct application to the distal intestinal tract for treating pouchitis. The Office Action has failed to establish any factual support for the assertion that direct application of the claimed dosage of azole compounds to the distal intestinal tract would be tolerated and/or effective for treating pouchitis.

The present application is based, at least in part, on the surprising discovery that local administration of high levels of anti-fungal azole compounds can be used to treat non-fungal induced mucositis. Prior to the present application, the distal components of non-fungal induced mucositis were not believed to be treatable by conventional dosing because of low concentrations of therapeutics, while high conventional oral dosing resulted in undesired side effects (see, for example, page 3, lines 6-17 of application as filed). Applicant respectfully submits that the Examiner's assertion of obviousness in view of the prior art stems from an improper application of hindsight reasoning based on the teachings of the present application.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the application in condition for allowance.

If there is a fee occasioned by this response, including an extension fee, that is not covered by the credit card payment, please charge any deficiency to Deposit Account No. 23/2825 under Docket No. C0875.70019US02.

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Respectfully submitted,

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